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**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA PHARMACEUTICALS LP and	)	
ASTRAZENECA UK LIMITED,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
AMNEAL PHARMACEUTICALS, LLC,	)	
AMNEAL HOLDINGS, LLC,	)	Civil Action No. _____
AMNEAL PHARMACEUTICALS HOLDING	)	
COMPANY, LLC,	)	
AMNEAL PHARMACEUTICALS OF NEW	)	
YORK, LLC, and	)	
AMNEAL PHARMACEUTICALS CO. INDIA	)	
PRIVATE LIMITED,	)	
	)	
Defendants.	)	
	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited

(collectively, "AstraZeneca"), for their complaint against Defendants Amneal Pharmaceuticals,

LLC (“Amneal Pharma”), Amneal Holdings, LLC (“Amneal Holdings”), Amneal Pharmaceuticals Holding Company, LLC (“Amneal Pharmaceutical Holding”), Amneal Pharmaceuticals of New York, LLC (“Amneal NY”), and Amneal Pharmaceuticals Co. India Private Limited (“Amneal India”) (collectively, “Amneal”), hereby allege as follows:

**THE PARTIES**

1. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of Delaware, having its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

2. Plaintiff AstraZeneca UK Limited is a company incorporated under the Laws of England and Wales, having a registered office at 2 Kingdom Street, London, England W2 6BD.

3. On information and belief, Amneal Pharma is a corporation organized under the laws of the State of Delaware, having a principal place of business at 440 U.S. Highway 22 East, Suite 104, Bridgewater, New Jersey 08807, and is the parent corporation of Amneal NY and Amneal India. Amneal Pharma is in the business of, among other things, manufacturing and marketing generic copies of branded pharmaceutical products throughout the United States including in this District.

4. On information and belief, Amneal Holdings is a corporation organized under the laws of the State of Delaware, and is the parent corporation of Amneal Pharma. Amneal Holdings is in the business of, among other things, manufacturing and marketing generic copies of branded pharmaceutical products throughout the United States including in this District.

5. On information and belief, Amneal Pharmaceutical Holding is a corporation organized under the laws of the State of Delaware, and is the parent corporation of Amneal Pharma. Amneal Pharmaceutical Holding is in the business of, among other things, manufacturing and marketing generic copies of branded pharmaceutical products throughout the United States including in this District.

6. On information and belief, Amneal NY is a corporation organized under the laws of the State of Delaware, having a principal place of business at 85 Adams Ave, Hauppauge, New York, 11788, and is a subsidiary of Amneal Pharma. Amneal NY is in the business of, among other things, manufacturing and marketing generic copies of branded pharmaceutical products throughout the United States including in this District.

7. On information and belief, Amneal India is an Indian corporation and a subsidiary of Amneal Pharmaceuticals, LLC, having a principal place of business at 882/1-871, Rajoda Village, Near Hotel Kankavati, Bavla Taluka, Ahmedabad-382220, Gujarat, India, and is a subsidiary of Amneal Pharma. Amneal India is in the business of, among other things, manufacturing and marketing generic copies of branded pharmaceutical products throughout the United States including in this District.

8. On information and belief, Amneal Pharma, Amneal Holdings, Amneal Pharmaceutical Holding, Amneal NY and Amneal India hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic pharmaceutical products.

### **JURISDICTION AND VENUE**

9. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. Jurisdiction is based

on 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(c), 1391(d), 1400(a) and 1400(b).

10. This Court has personal jurisdiction over Amneal Pharma because Amneal Pharma resides in this District and it has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being haled into court here. In addition, on information and belief, Amneal Pharma has had continuous and systematic contacts with this judicial district, including: (1) being registered to do business in New Jersey, (2) having its headquarters in New Jersey, (3) having branches of business in New Jersey, (4) conducting business within this judicial district, (5) directly, or indirectly, manufacturing, marketing, selling, and distributing generic drugs throughout the United States and in this judicial district, (6) purposefully has conducted and continues to conduct business in this judicial district, and (7) this judicial district is a likely destination of its generic products. Thus, Amneal Pharma is subject to general jurisdiction in New Jersey.

11. This Court has personal jurisdiction over Amneal Holdings because Amneal Holdings has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being haled into court here. In addition, on information and belief, Amneal Holdings has had continuous and systematic contacts with this judicial district, including: (1) engaging in the business of manufacturing, marketing, importing, selling and distributing pharmaceutical drug products, including generic drug products within this judicial district, (2) directly or indirectly, and in partnership and agency with its subsidiary Amneal Pharma, conducting business within this judicial district, and (3) directly or indirectly, and in partnership and agency with its subsidiary Amneal Pharma, manufacturing, marketing,

selling and distributing generic drugs throughout the United States and in this judicial district. Thus, Amneal Holdings is subject to general jurisdiction in New Jersey.

12. This Court has personal jurisdiction over Amneal Pharmaceutical Holding because Amneal Pharmaceutical Holding has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being haled into court here. In addition, on information and belief, Amneal Pharmaceutical Holding has had continuous and systematic contacts with this judicial district, including: (1) engaging in the business of manufacturing, marketing, importing, selling and distributing pharmaceutical drug products, including generic drug products within this judicial district, (2) directly or indirectly, and in partnership and agency with its subsidiary Amneal Pharma, conducting business within this judicial district, and (3) directly or indirectly, and in partnership and agency with its subsidiary Amneal Pharma, manufacturing, marketing, selling and distributing generic drugs throughout the United States and in this judicial district. Thus, Amneal Pharmaceutical Holding is subject to general jurisdiction in New Jersey.

13. This Court has personal jurisdiction over Amneal NY because Amneal NY has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being haled into court here. In addition, on information and belief, Amneal NY has had continuous and systematic contacts with this judicial district, including: (1) engaging in the business of manufacturing, marketing, importing, selling and distributing pharmaceutical drug products, including generic drug products within this judicial district, (2) directly or indirectly, and in partnership and agency with its parent corporation Amneal Pharma, conducting business within this judicial district, and (3) directly or indirectly, and in partnership and agency with its parent corporation Amneal Pharma, manufacturing, marketing, selling and

distributing generic drugs throughout the United States and in this judicial district. Thus, Amneal NY is subject to general jurisdiction in New Jersey.

14. This Court has personal jurisdiction over Amneal India because Amneal India has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being haled into court here. In addition, on information and belief, Amneal India has had continuous and systematic contacts with this judicial district, including: (1) engaging in the business of manufacturing, marketing, importing, selling and distributing pharmaceutical drug products, including generic drug products within this judicial district, (2) directly or indirectly, and in partnership and agency with its parent corporation Amneal Pharma, conducting business within this judicial district, and (3) directly or indirectly, and in partnership and agency with its parent corporation Amneal Pharma, manufacturing, marketing, selling and distributing generic drugs throughout the United States and in this judicial district. Thus, Amneal India is subject to general jurisdiction in New Jersey.

15. AstraZeneca has brought the following related actions in the United States District Court for the District of New Jersey: *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Handa Pharms., LLC and John Doe Entity*, Civil Action Nos. 08-cv-3773 (JAP) (TJB), 08-cv-5328 (JAP) (TJB) and 08-cv-5997 (JAP) (TJB) (“the Handa actions”); *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Accord Healthcare, Inc. and Intas Pharms., Ltd*, Civil Action Nos. 08-cv-4804 (JAP) (TJB) and 09-cv-0619 (JAP) (TJB) (“the Accord actions”); *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Anchen Pharmaceuticals Inc.*, Civil Action No. 10-cv-1835 (JAP) (TJB) (“the Anchen action”); *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Osmotica Pharmaceutical Corp.*, Civil Action No. 10-cv-4203 (JAP) (TJB) and 11-cv-2484 (JAP) (TJB) (“the Osmotica actions”); *AstraZeneca Pharms. LP and*

*AstraZeneca UK Ltd. v. Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.*, Civil Action Nos. 10-cv-4205 (JAP) (TJB) and 10-cv-4971 (JAP) (TJB) (“the Torrent actions”); and *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Mylan Pharmaceuticals Inc. and Mylan Inc.*, Civil Action No. 10-cv-5519 (JAP) (TJB) and 11-cv-2483 (JAP)(TJB) (“the Mylan actions”) (collectively “the closed actions”). All of these closed actions involve a claim by AstraZeneca of infringement of AstraZeneca’s United States Patent No. 5,948,437 (“the ’437 patent”), the same patent that is involved in the present action. The Handa and Accord actions were settled on the eve of trial. The Anchen, Osmotica, Torrent and Mylan actions were tried before the Honorable Joel A. Pisano in October 2011. In a March 29, 2012 Opinion, Judge Pisano found all asserted claims of the ’437 patent valid and infringed. Appeals from the Osmotica, Torrent and Mylan decisions are presently pending before the United States Court of Appeals for the Federal Circuit.

16. AstraZeneca has also brought the following, related actions in the United States District Court for the Southern District of New York: *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. IntelliPharmaCeutics Corporation and IntelliPharmaCeutics International Inc.*, Civil Action Nos. 11-cv-4498 (RJS)(KNF) and 12-cv-2855 (RJS)(KNF). These actions also involve the same patent-in-suit. These actions were settled and dismissed.

### **CLAIMS FOR RELIEF**

#### **Count 1: Direct Infringement By Amneal Pharma**

17. AstraZeneca realleges paragraphs 1-16 above as if set forth specifically herein.

18. Plaintiff AstraZeneca Pharmaceuticals LP is the holder of New Drug Application (“NDA”) No. 22-047, by which the FDA first granted approval for 50 mg, 150 mg,

200 mg, 300 mg and 400 mg extended release tablets containing the active ingredient quetiapine (11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl] dibenzo [b,f][1,4] thiazepine) fumarate. The quetiapine fumarate extended release tablets described in NDA No. 22-047 are sold by AstraZeneca in the United States under the trademark SEROQUEL XR®.

19. Plaintiff AstraZeneca UK Limited is the owner of the '437 patent, entitled "Pharmaceutical Compositions Using Thiazepine," which was duly and legally issued by the United States Patent and Trademark Office on September 7, 1999 upon assignment from the inventors Bhavnish V. Parikh, Robert J. Timko and William J. Addicks. A copy of the '437 patent is attached as Exhibit A. The '437 patent claims, *inter alia*, sustained release formulations of quetiapine fumarate, including SEROQUEL XR® extended release tablets, and processes for preparing and using such formulations.

20. The '437 patent will expire on May 28, 2017.

21. By letter dated July 3, 2012 purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B) (the "Notice Letter"), Amneal Pharma notified AstraZeneca that it had submitted ANDA No. 204112 to the U.S. Food and Drug Administration ("FDA") seeking the approval of the FDA to commercially manufacture, market, use and sell, prior to the expiration of the '437 patent, quetiapine fumarate extended release tablets in 50 mg, 150 mg, 200 mg, 300 mg and 400 mg strengths as generic versions of AstraZeneca's SEROQUEL XR® 50 mg, 150 mg, 200 mg, 300 mg and 400 mg extended release tablets. AstraZeneca received this letter on July 5, 2012.

22. In the Notice Letter, Amneal Pharma alleged that certain claims of the '437 patent will not be infringed by its proposed generic quetiapine fumarate extended release



tablets. Amneal Pharma did not allege in the Notice Letter that its proposed generic quetiapine fumarate extended release tablets will not infringe claims 1, 10 and 13-14 of the '437 patent.

23. Amneal Pharma also alleged in the Notice Letter that certain claims of the '437 patent are invalid for obviousness under 35 U.S.C. § 103(a). Amneal Pharma did not allege in the Notice Letter that claims 3-9, 11, 12 and 15 of the '437 patent are invalid.

24. Amneal Pharma has infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 204112 seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '437 patent, or the use of which is claimed in the '437 patent, prior to the expiration of that patent.

25. The quetiapine fumarate extended release tablets for which Amneal Pharma seeks approval under ANDA No. 204112 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

26. The commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, of Amneal Pharma's quetiapine fumarate extended release tablets will directly or indirectly infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a), (b) or (c).

27. AstraZeneca is entitled to full relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 204112 be a date that is not earlier than the later of May 28, 2017, the expiration date of the '437 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled.

**Count 2: Infringement by Amneal Holdings**

28. AstraZeneca realleges paragraphs 1-27 above as if set forth specifically herein.

29. On information and belief, Amneal Holdings initiates, directs and controls the activities of its subsidiary company, Amneal Pharma with regard to ANDA No. 204112 and the quetiapine fumarate extended release tablets described therein.

30. On information and belief, Amneal Holdings, through Amneal Pharma as its agent, initiated, directed and controlled the preparation and filing of ANDA No. 204112 with the FDA.

31. On information and belief, Amneal Holdings has infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by initiating, directing and controlling the preparation and filing of ANDA No. 204112.

32. On information and belief, in the event that the FDA approves ANDA No. 204112, Amneal Holdings stands to benefit directly from such approval by being able to commercially manufacture and distribute the quetiapine fumarate extended release tablets that are the subject of the ANDA.

33. The quetiapine fumarate extended release products for which Amneal Holdings, through Amneal Pharma as its agent, seeks approval under ANDA No. 204112 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

34. The commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, by Amneal Holdings of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 204112 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

35. The commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, of Amneal Holdings' quetiapine fumarate

extended release tablets will directly or indirectly infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a), (b) or (c).

36. AstraZeneca is entitled to full relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 204112 be a date that is not earlier than the later of May 28, 2017, the expiration date of the '437 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled.

**Count 3: Infringement by Amneal Pharmaceutical Holding**

37. AstraZeneca realleges paragraphs 1-36 above as if set forth specifically herein.

38. On information and belief, Amneal Pharmaceutical Holding initiates, directs and controls the activities of its subsidiary company, Amneal Pharma with regard to ANDA No. 204112 and the quetiapine fumarate extended release tablets described therein.

39. On information and belief, Amneal Pharmaceutical Holding, through Amneal Pharma as its agent, initiated, directed and controlled the preparation and filing of ANDA No. 204112 with the FDA.

40. On information and belief, Amneal Pharmaceutical Holding has infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by initiating, directing and controlling the preparation and filing of ANDA No. 204112.

41. On information and belief, in the event that the FDA approves ANDA No. 204112, Amneal Pharmaceutical Holding stands to benefit directly from such approval by being able to commercially manufacture and distribute the quetiapine fumarate extended release tablets that are the subject of the ANDA.

42. The quetiapine fumarate extended release products for which Amneal Pharmaceutical Holding, through Amneal Pharma as its agent, seeks approval under ANDA No. 204112 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

43. The commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, by Amneal Pharmaceutical Holding of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 204112 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

44. The commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, of Amneal Pharmaceutical Holding's quetiapine fumarate extended release tablets will directly or indirectly infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a), (b) or (c).

45. AstraZeneca is entitled to full relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 204112 be a date that is not earlier than the later of May 28, 2017, the expiration date of the '437 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled.

**Count 4: Infringement by Amneal NY**

46. AstraZeneca realleges paragraphs 1-45 above as if set forth specifically herein.

47. On information and belief, Amneal Pharma initiates, directs and controls the activities of its subsidiary company, Amneal NY with regard to ANDA No. 204112 and the quetiapine fumarate extended release tablets described therein.

48. On information and belief, Amneal NY, under the control of Amneal Pharma was involved with the preparation and filing of ANDA No. 204112 with the FDA.

49. On information and belief, Amneal NY has infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by its involvement with the preparation and filing of ANDA No. 204112.

50. On information and belief, in the event that the FDA approves ANDA No. 204112, Amneal NY stands to benefit directly from such approval by being able to commercially manufacture and distribute the quetiapine fumarate extended release tablets that are the subject of the ANDA.

51. The quetiapine fumarate extended release products for which Amneal NY, through Amneal Pharma as its parent company, seeks approval under ANDA No. 204112 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

52. The commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, by Amneal NY of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 204112 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

53. The commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, of Amneal NY's quetiapine fumarate extended release tablets will directly or indirectly infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a), (b) or (c).

54. AstraZeneca is entitled to full relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 204112 be a date that is not earlier than the later of May 28, 2017, the expiration date of the '437 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled.

**Count 5: Infringement by Amneal India**

55. AstraZeneca realleges paragraphs 1-54 above as if set forth specifically herein.

56. On information and belief, Amneal Pharma initiates, directs and controls the activities of its subsidiary company, Amneal India with regard to ANDA No. 204112 and the quetiapine fumarate extended release tablets described therein.

57. On information and belief, Amneal India, under the control of Amneal Pharma was involved with the preparation and filing of ANDA No. 204112 with the FDA.

58. On information and belief, Amneal India has infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A) by its involvement with the preparation and filing of ANDA No. 204112.

59. On information and belief, in the event that the FDA approves ANDA No. 204112, Amneal India stands to benefit directly from such approval by being able to commercially manufacture and distribute the quetiapine fumarate extended release tablets that are the subject of the ANDA.

60. The quetiapine fumarate extended release products for which Amneal India, through Amneal Pharma as its parent company, seeks approval under ANDA No. 204112 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

61. The commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, by Amneal India of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 204112 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).

62. The commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, of Amneal India's quetiapine fumarate extended release tablets will directly or indirectly infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a), (b) or (c).

63. AstraZeneca is entitled to full relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 204112 be a date that is not earlier than the later of May 28, 2017, the expiration date of the '437 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled.

**Count 6: Exceptional Case**

64. AstraZeneca realleges paragraphs 1-63 as if set forth specifically herein.

65. Prior to filing ANDA No. 204112, Amneal was aware of the existence of the '437 patent, and, upon information and belief, was aware that the filing of ANDA No. 204112, including a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '437 patent, infringed that patent.

66. Prior to sending the Notice Letter, Amneal was aware of Judge Pisano's decision in the related cases identified in paragraph 15. In fact, Amneal acknowledged the decision in a footnote in the Notice Letter. That decision sets forth Judge Pisano's opinion that the '437 patent remains valid and is infringed by other generic drug manufactures that had been seeking approval to market and sell generic sustained-release quetiapine. That decision put Amneal on notice that their allegations of non-infringement and invalidity are devoid of an objective good faith basis in either the facts or the law and should not be maintained.

67. This case is an exceptional one, and AstraZeneca is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the '437 patent remains valid and enforceable, and that this patent has been infringed by Defendants;

(b) A judgment declaring that the effective date of any approval of ANDA No. 204112 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date that is not earlier than the later of May 28, 2017, the expiration date of the '437 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled;

(c) A permanent injunction against any infringement of the '437 patent by Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them;

(d) A judgment that this is an exceptional case, and that Plaintiffs are entitled to an award of their reasonable attorney fees pursuant to 35 U.S.C. § 285;

(e) To the extent that Defendants have committed any acts with respect to the subject matter claimed in the '437 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which this Court should treble pursuant to 35 U.S.C. § 284;

(f) Costs and expenses in this action; and

(g) Such other relief as this Court may deem proper.

Dated: August 2, 2012

Respectfully submitted,



By: /s/ John E. Flaherty

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Attorneys for Plaintiffs  
AstraZeneca Pharmaceuticals LP and  
AstraZeneca UK Limited

**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matters in controversy are not the subject of any other action pending in any other court or of any pending arbitration or administrative proceeding, with the exception of the following related lawsuits, identified in Paragraph 15 of this Complaint involving different defendants but the same patent-in-suit, that are currently on appeal to the Federal Circuit:

- *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Osmotica Pharmaceutical Corp.*, Civil Action Nos. 10-cv-4203 (JAP) (TJB) and 11-cv-2484 (JAP) (TJB);
- *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.*, Civil Action Nos. 10-cv-4205 (JAP) (TJB) and 10-cv-4971 (JAP) (TJB); and
- *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Mylan Pharmaceuticals Inc. and Mylan Inc.*, Civil Action No. 10-cv-5519 (JAP) (TJB) and 11-cv-2483 (JAP)(TJB).

Dated: August 2, 2012

Respectfully submitted,

By: /s/ John E. Flaherty

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